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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,582	12/12/2003	Wolfgang A. Renner	1700.0030003/JAG/BJD/SJE	4575
26111	7590	08/22/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,582

Applicant(s)

RENNER ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-97 is/are pending in the application.
- 4a) Of the above claim(s) 70-72, 79 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 50-69, 73-78 and 81-97 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 50-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/16/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 50-78, 81-97, drawn to array of allergen attached to core particle by nonpeptide bond, classified in class 424, subclass 193.1 for example. If this group is elected, species election of core is further required.
- II. Claims 79-80, drawn to recombinant packaging-defective alphavirus with leucine-zipper E2 protein, classified in class 435, subclass 235.1 for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (group I) as claimed does not require the particulars of the subcombination as claimed because the combination is not limited to an alphavirus particle, see as evidence claims 50 and 59. The subcombination has separate utility such as attaching a targeting moiety to a recombinant alphavirus vector.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Group I contains claims directed to the following patentably distinct species of core particles:

- (a) virus-like materials of claim 51,
- (b) synthetic polymer of claim 70,
- (c) lipid micelle of claim 70, and
- (d) metal of claim 70.

The species are independent or distinct because the core particles are chemically and structurally distinct, and a reference teaching one of the species would not necessarily render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 50, 75, 81-90 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

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During a telephone conversation with Simon Elliott on 8/15/2006 a provisional election was made with traverse to prosecute the invention of group I, species A, claims 50-69, 73-78, 81-97. Affirmation of this election must be made by applicant in replying to this Office action. Claims 70-72, 79, and 80 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Generic claims 50, 75, 81-90 have been examined only to the extent that they read upon the elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Claims 50-69, 75-78, 81-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims involve "proteins suited to induce an immune response against allergens." The only discussion of proteins in this category involves proteins which are allergens. However, Miescher et al (Molecular Aspects of Medicine 23:413-462, 2002) is cited as evidence that other types of proteins are involved in inducing immune response against allergens. Therefore it is not clear what scope is encompassed by "proteins suited to induce an immune response against

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allergens.” This rejection could be obviated if the claims were amended to recite “wherein said antigen is an allergenic protein.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53, 69, 73-78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Crameri et al WO 9828624. See page 4, line 36 through page 7, line 17 and Table 2.

Double Patenting

Claims 50-53, 57-62, 66- 69, 73-78, 81-94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6964769. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims involve or encompass allergens bonded to a type of HBV particle, see especially patent claims 3, 5, 7, and 8.

Claims 50-69, 73-78, 81-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 47, 48, 52-55, 57, 63 of copending Application No. 10/563944. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims involve allergens bound to virus-like particles.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 50-69, 73-78, 81-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 13, 100, 102, 107, 108 of copending Application No. 10/550518. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims involve allergens bound to virus-like particles.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following references are cited as of interest. Harris et al teaches a similar product, but the allergen is bound to the particle via peptide bond. Murray US 6827937 teaches a similar product, but is not available as prior art. Mastico et al US 5698424 teaches nonpeptide bonding of antigens to phage particles, but does not teach allergens as appropriate antigens. No particular motivation was found to combine the teachings of these references.

The following references are also cited as of interest. Ormstad et al teaches allergens non-covalently bound to a core particle forming an orderly and repetitive array, see figure 2. US 6180771 and US 5916818 teach synthetic polymer microtiter plates or metallic microparticles with bound allergens forming an orderly and repetitive array, see column 10, lines 46-60 (6180771) or column 4, line 26 – column 5, line 18 (5916818). JP09202735 teaches liposomes displaying allergens, which would have been inherently

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a repetitive array because of the dispersion of the immobilized antigen in the spherical liposome membrane.

Information Disclosure Statement

The relatively concise IDS of 6/14/2004 is acknowledged with gratitude, and has been considered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MARY E. MOSHER, PH.D.
PRIMARY EXAMINER